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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/769,360 | 01/26/2001 | Peng C. Tang | 038602/1081 | 4781 |

7590 08/19/2002

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EXAMINER

COLEMAN, BRENDA LIBBY

| ART UNIT | PAPER NUMBER |
|----------|--------------|
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1624

DATE MAILED: 08/19/2002

7

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/769,360

Applicant(s)
TANG et al.

Examiner
Brenda Coleman

Art Unit
1624



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Jun 10, 2002.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17, 20-28, 31-34, and 36-39 is/are pending in the application.
- 4a) Of the above, claim(s) 3-9, 13, 14, 17, 20-25, and 36 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 31 is/are allowed.
- 6) ☒ Claim(s) 1, 2, 10-12, 16, 26-28, 32-34, and 37-39 is/are rejected.
- 7) ☒ Claim(s) 15 is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 3 6) ☐ Other:

Art Unit: 1624

DETAILED ACTION

Claims 1-17, 20-28, 31-34 and 36-39 are pending in the application.

Election/Restriction

1. Applicant's election with traverse of III in Paper No. 6 is acknowledged.

In view of the applicants' remarks and upon further consideration the claims of Group I as it pertains to formulae I and III and Group ^{BC 10-16-02}V will be examined along with the elected invention of Group III.

The requirement with respect to Groups II, IV, ^{BC 10-16-02}V, ~~VI~~, VII and VIII is still deemed proper and is herein maintained.

2. Claims 3-9, 13, 14, 17, 20-25 and 36 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 6.
3. Claims 1, 2, 10-12, 16, 26-28, 32-34 and 37-39 are rejected as being drawn to an improper Markush group. The recited compounds, while possessing a common utility, differ widely in structure and are not art-recognized equivalents and are thus, independently distinct for the reasons set forth in the restriction requirement. The Markush group represented by the structural formulae (I), (II), and (III) have variably different definitions, rendering the claims clearly improper.

Art Unit: 1624

Priority

4. When a non-provisional application claims the benefit under 35 USC 120 of a prior application, which in turn claims the benefit of a provisional application, the first sentence of the specification should read, e.g., "This application is a divisional of U.S. Application No. 09/071,682, filed on May 1, 1998, now U.S. Patent 6,204,267, which claims the benefit of U.S. Provisional Application No. 60/060,152, filed on September 26, 1997 and U.S. Provisional Application No. 60/045,351, filed on May 2, 1997." should appear as the first sentence of the description.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 1 and 2 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The quinazoline-based compound substituted at the 5-position with an optionally substituted five-membered or six-membered aryl or heteroaryl ring is of indeterminate scope for which there is no support other than the compounds of formula (III) which possess an five-membered or six-membered heteroaryl at the 5-position of the quinazoline ring.

Art Unit: 1624

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 1, 2, 10-12, 26, 28, 33, 34 and 37-39 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The following reasons apply:

- a) Claims 1 and 2 are vague and indefinite in that it is not known what is meant by “a quinazoline-based compound substituted at the 5-position with an optionally substituted five-membered or six-membered aryl or heteroaryl ring”.
- b) Claims 10 and 11 recite the limitation "structure (I)" in the method claim. There is insufficient antecedent basis for this limitation in the claim.
- c) Claim 10 is vague and indefinite in that it is not known what is meant by the variable R in structure (I) which is not defined within the claim.
- d) Claim 10 is vague and indefinite in that it is not known what is meant by the multiple different definitions for the variable n, i.e. in (b) where n is 0, 1, 2, 3, or 4; in (vi) where n is 0 or 1; and in (vii) where n is 0 or 1.
- e) Claim 10 is vague and indefinite in that the paragraphs labeled (e) and (f) are missing, i.e. the paragraph labels are (a), (b), (c), (d), (g), (h) and (i).
- f) Claim 11 is vague and indefinite in that it is not known what is meant by the variable R in structures (I) and (III) which is not defined within the claim.

Art Unit: 1624

- g) Claim 11 is vague and indefinite in that it is not known what is meant by the definition for the variable R_2 since there is no variable R_2 in structures (I) or (III).
- h) Claim 12 is vague and indefinite in that it is not known what is meant by the variable R in structure (V) which is not defined within the claim.
- i) Claim 12 is vague and indefinite in that it is not known what is meant by the definition for the variable R_2 since there is no variable R_2 in structure (V).
- j) Claim 26 is vague and indefinite in that it is not known what is meant by the variable n in structure (I) which is not defined within the claim.
- k) Claim 26 is vague and indefinite in that the paragraph labeled (ii) is missing, i.e. the paragraph labels are (i), (iii), (iv), (v), (v), (vi) and (vii).
- l) Claim 26 is vague and indefinite in that it is not known what is meant by the two paragraphs labeled (v).
- m) Claim 26 is vague and indefinite in that it is not known what is meant by the two different definitions for the variables X_2 and X_3 , i.e. in (iv)(c) where X_2 and X_3 are independently selected from the group consisting of hydrogen and saturated or unsaturated alkyl; and in (v)(c) where X_2 and X_3 are independently selected from the group consisting of hydrogen, saturated or unsaturated alkyl and five-membered or six-membered aryl or heteroaryl ring moieties.
- n) Claim 28 is vague and indefinite in that it is not known what is meant by the two different definitions for the variables R_3 , R_4 and R_5 , i.e. in (d) where R_3 , R_4 and R_5

Art Unit: 1624

are independently selected from the group consisting of (i) hydrogen; and (ii) saturated or unsaturated alkyl; (iii) NX_3X_4 and in (e) where R_3 , R_4 and R_5 are independently selected from the group consisting of (i) hydrogen, provided that at least one of R_3 , R_4 , R_5 is a non-hydrogen moiety if R_2 is $-NH_2$; (ii) saturated or unsaturated alkyl; (iii) NX_5X_6 ; (iv) halogen or trihalomethyl; (v) $C(X_7)_3$; and (vi) methoxy.

- o) Claim 33 is dependent upon two canceled claims, i.e. claims 29 and 30.
- p) Claims 34 and 37-39 vague and indefinite in that it is not known what is meant by the multiple different definitions for the variable n, i.e. in (b) where n is 0, 1, 2, 3, or 4; in (vi) where n is 0 or 1; and in (vii) where n is 0 or 1.
- q) Claim 37 is dependent upon a canceled claim, i.e. claim 35.
- r) Claim 37 is dependent upon a non-elected claim, i.e. claim 36.

Claim Objections

7. Claims 15 and 16 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Allowable Subject Matter

8. Claim 31 is allowed. None of the prior art of record nor a search in the pertinent art area teaches the 5-pyrroloquinazoline compounds of the instant invention.

Art Unit: 1624

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brenda Coleman whose telephone number is (703) 305-1880. The examiner can normally be reached on Mondays and Tuesdays from 9:00 AM to 3:00 PM and from 5:30 PM to 7:30 PM and on Wednesday thru Friday from 9:00 AM to 6:00 PM.

The fax phone number for this Group is (703) 308-4734 for "unofficial" purposes and the actual number for **OFFICIAL** business is **308-4556**.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.



Brenda Coleman
Primary Examiner AU 1624
August 16, 2002